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April 3, 2002

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INDEPENDENT

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson:

I am writing to urge you to take action to halt the manufacturing and sale of nicotine lollipops in the United States. These products can be purchased at a growing number of pharmacies and by children without a prescription over the internet. Moreover, the active ingredient in nicotine lollipops is unapproved and may be associated with a rare liver disorder in children.

A growing market of nicotine products is developing outside virtually any government regulation. I am not opposed to innovative strategies for smoking cessation. However, I believe such products must be shown to be safe and effective before they are widely distributed. I urge you to take immediate action to prevent the sale of nicotine lollipops and similar products until they are determined to be safe and effective as required under the law.

Nicotine Lollipops

Nicotine lollipops are currently being produced by pharmacists, some of whom have learned about the products at national conferences.¹ The lollipops are then sold under a variety of names, including NicoStop, NicoPop, Likatine, NoSmoke, and simply Nicotine Lollipop. They are also sold in a variety of flavors, including many that are likely to appeal to children. Available flavors include Apricot, Banana Cream, Blackberry, Blueberry, Bubble Gum, Butter Rum, Cherry, Cinnamon Apple, Cinnamon Citrus, Cinnamon, Eggnog, Grape, Green Apple, Green Apple-Cherry, Hawaiian Coconut, Lemon, Lemon-Lime, Licorice, Margarita, Mixed Mint,

¹*Nicotine-Laced Suckers Help Smokers Quit a Lick at a Time*, Spokesman-Review (Feb. 25, 2002).

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Orange, Orange-Pineapple, Peach, Peppermint, Pina Colada, Pineapple Splash, Raspberry, Root Beer, Strawberry, Strawberry-Banana, Spearmint, Sweet Citrus, Tangerine, Tequila Sunrise, Tropical Punch, Tutti Fruitti, Very Berry, and Watermelon.

These flavors and sweeteners are used to mask the taste of nicotine. As one Washington State pharmacist said, "We do a good job of flavoring and masking any taste of the drug."² Another pharmacy technician in Indiana said, "They taste just like Dum Dum suckers. . . you can't even taste the nicotine at all."³

Nicotine lollipops are easily available to children. While some pharmacies appear to require a prescription, my staff found several web sites that sell these products without a doctor's order. The cost is approximately \$2 to \$3 per lollipop. As one news station told viewers, "[Y]ou get five in a pack for 12 dollars and they should last you a couple of days, plus you don't need a prescription."⁴ A pharmacist in Washington State has already reported that "we've had high school kids come in and inquire about our nicotine lollipops."⁵

Legal and Policy Concerns

I have several concerns about nicotine lollipops. First, these products may pose serious risks to children. Nicotine lollipops are a new product, so there have been no studies that I am aware of that examine the use of these products by children. Nevertheless, the potential for use by children is obvious. An addictive drug should not be masked by sweeteners and sold as a lollipop without a thorough review by FDA and strict safeguards to prevent inappropriate underage use. Prior to approving the nicotine patch and gum, FDA analyzed the public health impact of the products and took steps to assure that marketing and labeling would discourage inappropriate use by youth. The absence of FDA approval for nicotine lollipops, by contrast, means a public health analysis and a plan to protect children do not exist. Even if these products were to be proven safe and effective for adults, they should not be allowed on the market without safeguards to prevent children and adolescents from becoming addicted to nicotine, which could lead to more, not less, youth smoking.

²*Nicotine-Laced Suckers Help Smokers Quit a Lick at a Time*, The Spokesman-Review (Feb. 25, 2002).

³*Lollipop, Lollipop, Oh Nicotine Lollipop*, Click2Houston.com (Nov. 15, 2001) (online at www.click2houston.com/sh/health/stories/health-108131920011115-121153.html).

⁴*Special Lollipops Help Smokers Kick The Habit*, WCJB News (online at www.wcjb.com) (Accessed Mar. 13, 2002).

⁵*Nicotine Lollipop May Help Smokers Lick the Habit*, Associated Press (Jan. 17, 2002).

Second, the active ingredient in nicotine lollipops is a potentially unsafe drug, nicotine salicylate. Like many other nicotine compounds, nicotine salicylate is considered a toxic chemical by EPA for the purpose of the Emergency Planning and Community Right-to-Know Act of 1986.⁶ One component of nicotine salicylate is salicylate, which has been associated with the devastating liver disorder of Reye's Syndrome in children.⁷ While salicylate in aspirin has most frequently been linked to Reye's Syndrome, salicylate in other compounds may pose similar risks.

The safety of nicotine salicylate has not been established by FDA. Under the Federal Food, Drug, and Cosmetic Act (FDCA), such a review must occur prior to the lawful sale of nicotine lollipops. Section 503A of the FDCA, the section of the law regulating pharmacy compounding, permits pharmacies to produce small quantities of unapproved drugs only if the bulk drug substance is a component of an approved drug, is found in the *United States Pharmacopeia* or National Formulary monograph, or is named by FDA in a separate list.⁸ Nicotine salicylate, however, does not meet any of these criteria. It is not found in any approved drug, in the *United States Pharmacopeia* or National Formulary monograph,⁹ or in FDA's separate list.¹⁰

Third, nicotine lollipops are being marketed on the basis of health claims that have not been approved by FDA or substantiated scientifically. Pharmacies advertise that nicotine lollipops function as treatment for abstinent smokers in the same way as nicotine gum and nicotine patches, two FDA-approved products. For example, one pharmacy says:

⁶Environmental Protection Agency, *List of Toxic Chemicals Within the Nicotine and Salts Category* (June 1999).

⁷AP Sarnaik, *Reye's Syndrome: Hold the Obituary*, *Critical Care Medicine*, 1674-6 (Aug. 1, 1999) ("Although the exact causative mechanism has remained elusive, many meticulous, independent epidemiologic studies have shown a strong association between the use of salicylates during the antecedent viral illness and the development of [Reye's Syndrome].")

⁸The validity of section 503A is currently under review by the Supreme Court. If section 503A is ruled invalid, pharmacy compounding that results in new drug products such as nicotine lollipops would be illegal even if the pharmacist used approved bulk drug substances as ingredients. See Petitioner's Petition for a Writ of Certiorari at 4, *Thompson vs. Western States Medical Center*, No. 01-344 (U.S. August 2001).

⁹Email from U.S.P. staff to minority staff of the Government Reform Committee (Mar. 26, 2002).

¹⁰21 CFR 55564.

The lollipops, gum, and patches are intended to help smokers quit their tobacco habit by suppressing symptoms of nicotine withdrawal. All of the replacement methods allow the individual to start with larger doses of nicotine and wean themselves over a period of time. We have found that Nicotine Lollipops used by themselves or in conjunction with other products greatly assist those individuals who really want to quit smoking.¹¹

Another pharmacy tries to convince customers that nicotine lollipops are better than other smoking cessation products:

[Nicotine lollipops] allow the individual to deal with the hand to mouth fixation by keeping the hands busy—no other smoking cessation product on the market does this! The patch provides a slow steady stream of nicotine all day long, but do not provide for pulses of nicotine to calm stressful cravings. Also, many people are intolerant to the adhesive on the patch which leads to an itchy or burning rash. So, why not use the gum? Most people do not chew it properly and it leads to larger doses of nicotine being released and it frequently can lead to headaches, heart palpitations, and other problems. Another prescription alternative available to smokers who want to quit is the Nicotrol® inhaler. It provides nicotine through an inhalation-type device, which can sometimes cause throat irritation and a bad taste in the mouth. Not to mention, it is fairly costly at approximately \$50.00 per unit.¹²

A third pharmacy even claims nicotine sugar-free lollipops are “ideal for persons with diabetes.”¹³

Such health claims are not supported by evidence. In contrast to the many studies establishing the effectiveness of the nicotine patch, gum, and inhaler, I am not aware of a single published study on nicotine lollipops. These unproven claims may deceive consumers and promote a potentially unsafe drug. Under the FDCA, it is simply illegal to market a drug with health claims that have not been approved by FDA.

Other Nicotine Products

Some of the same concerns raised by nicotine lollipops apply to other nicotine products

¹¹*Nicotine Lollipops*, Birds Hill Pharmacy, (online at www.birdshill.com/lollipop.htm) (Accessed Mar. 25, 2002).

¹²*Stop Smoking?? NOW YOU CAN WITH NICOTINE LOLLIPOPS!*, Rice Drug, (online at www.ricedrugs.com/compounding/smoking.htm) (Accessed Mar. 25, 2002).

¹³*Nicotine Lollipops*, Rx Options, (online at www.rx-options.com/Nicotine.cfm) (Accessed Mar. 25, 2002).

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being sold without government oversight. In addition to lollipops, my staff purchased “nicotine lip balm” from a compounding pharmacy. This product promises, “It looks like a plastic ‘Chapstick’ but it contains a dose of nicotine in a sweet flavored base.” Each tube allegedly “provides hundreds of small doses – equivalent to approximately 100 cigarette breaks.”¹⁴

Advertisements for nicotine water can also be seen on the internet.¹⁵ Described as a smoking cessation aid and sold as a dietary supplement, this product promises, “all you will taste is the water.”

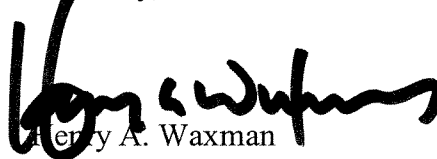
I believe FDA should take the unequivocal position that any product containing nicotine and making health claims must be found safe and effective by the Agency before it can be lawfully marketed.

Conclusion

When the Supreme Court stopped FDA’s regulation of tobacco products in 2000, the Court did not intend for the agency to abdicate all responsibility over products containing nicotine as well. Nicotine lollipops may attract children to an addictive drug, are potentially dangerous, and are marketed unlawfully. I urge you to take immediate action to halt their distribution and the distribution of similar products until they are proven safe and effective.

I would appreciate being informed about your plans with respect to these products by April 29, 2002.

Sincerely,



Henry A. Waxman
Ranking Minority Member

¹⁴The Compounder, *Nicotine Lip Balm* (March 2002).

¹⁵*Nicotine Water*, www.nicotinewater.com (Accessed Mar. 25, 2002).